

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P.,)	
GALDERMA S.A. and GALDERMA)	
RESEARCH AND DEVELOPMENT,)	
S.N.C.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 10-00045-JJF
)	
TOLMAR INC.,)	
)	
Defendant.)	
_____)	

TOLMAR INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant Tolmar Inc. (hereinafter "Tolmar") hereby answers the Complaint of Plaintiffs Galderma Laboratories, L.P., Galderma S.A. and Galderma Research and Development, S.N.C. (hereinafter collectively, "Plaintiffs"), as follows:

JURISDICTION AND PARTIES

1. Tolmar lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies these allegations.
2. Tolmar lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies these allegations.
3. Tolmar lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies these allegations.
4. Admitted.

5. Admitted.

6. Admitted.

COUNT I FOR PATENT INFRINGEMENT

7. Tolmar incorporates by reference its responses to paragraphs 1-6.

8. Tolmar admits that U.S. Patent No. 7,579,377 (“the ‘377 patent”) is entitled “Administration of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders,” lists Michael Graeber and Janusz Czernielewski as the named inventors, was issued on August 25, 2009, and will expire on February 23, 2025. Tolmar admits that a copy of the ‘377 patent and the Issue Notification for the ‘377 patent are attached to the Complaint. Tolmar denies the remaining allegations in Paragraph 8.

9. Tolmar admits that the Orange Book lists “Galderma Labs LP” as the holder of an approved New Drug Application (“NDA”) No. 21-753 for Differin[®] topical gel including the active ingredient of adapalene at a strength of 0.3%. Tolmar admits that the Orange Book lists an approval date for NDA 21-753 of June 19, 2007. Tolmar admits that the ‘377 patent is listed in the Orange Book for NDA 21-752. Tolmar denies the remaining allegations in Paragraph 9.

10. Tolmar admits that the Orange Book lists “Galderma Labs LP” as the holder of NDAs for a 1% dosage topical cream, a 1% topical gel and a 3% dosage topical gel each including the active ingredient adapalene and each having the proprietary name Differin[®]. Tolmar denies the remaining allegations in Paragraph 10.

11. Tolmar admits that it submitted to the FDA an Abbreviated New Drug Application (“ANDA”) which was assigned ANDA No. 200298. Tolmar admits that its application designated as ANDA No. 200298 was submitted to obtain approval to engage in commercial manufacture, use, sale, offer for sale or import of Tolmar’s Adapelene Gel 0.3%, containing 0.3% adapelene (“the Tolmar Gel”) in the U.S. before the expiration of the ‘377 patent. Tolmar denies the remaining allegations in Paragraph 11.

12. Tolmar admits that ANDA No. 200298 includes a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV), which asserts that the claims of the ‘377 patent will not be infringed by the manufacture, use, sale, offer for sale or import of the Tolmar Gel. Tolmar denies the remaining allegations in Paragraph 12.

13. Tolmar admits that it sent to Plaintiffs, Galderma Laboratories LP and Galderma Research and Development, S.N.C. a letter dated December 10, 2009 notifying those Plaintiffs of Tolmar’s ANDA No. 200298, and providing information pursuant to 21 U.S.C. §355(j)(2)(B)(i) and/or (ii). Tolmar admits that ANDA No. 200298 includes a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV), which asserts that the claims of the ‘377 patent will not be infringed by the manufacture, use, sale, offer for sale or import of the Tolmar Gel. Tolmar denies the remaining allegations in Paragraph 13.

14. Denied.

15. Denied.

16. Tolmar admits that ANDA No. 200298 includes a request to the FDA for approval of at least one indication for the Tolmar Gel. Tolmar denies the remaining allegations Paragraph 16.

17. Tolmar admits that it intends that some physicians will prescribe the Tolmar Gel in accordance with the indication(s) approved by the FDA. Tolmar denies the remaining allegations Paragraph 17.

18. Denied.

COUNT II FOR DECLARATORY JUDGMENT

19. Tolmar incorporates by reference its responses to paragraphs 1-18.

20. Admitted.

21. Denied.

22. Denied.

23. Denied.

24. Denied.

* * *

Tolmar denies every allegation not expressly admitted herein. Tolmar further denies that Plaintiffs are entitled to the relief requested.

TOLMAR'S AFFIRMATIVE DEFENSES

Tolmar hereby raises the following affirmative defenses to the claims alleged in the Complaint based on knowledge or information known or available at this time, or believed by Tolmar to be true at this time.

First Affirmative Defense
(Failure to State a Claim Upon Which Relief May Be Granted)

Count I and/or Count II of the Complaint fails to state a claim upon which relief may be granted.

Second Affirmative Defense
(Non-Infringement of the '377 Patent)

Tolmar has not directly or indirectly infringed any valid claim of the '377 patent, literally or under the doctrine of equivalents, by making, using, selling, offering for sale or importing any product into the United States that is the subject of Tolmar's ANDA No. 200298, nor do Tolmar's activities relating to the filing of ANDA No. 200298 result in infringement of any valid claim of the '377 patent.

Third Affirmative Defense
(Prosecution History Estoppel)

The doctrine of prosecution history estoppel bars the expansion of one or all of the claims of the '377 patent to encompass, under the doctrine of equivalents, the Tolmar Gel. Therefore, Tolmar will not directly or indirectly infringe any valid claim of the '377 patent, under the doctrine of equivalents, by making, using, selling, offering for sale or importing the Tolmar Gel into the United States, nor do Tolmar's activities relating to the filing of ANDA No. 200298 result in infringement of any valid claim of the '377 patent.

Fourth Affirmative Defense
(Invalidity of the '377 Patent)

One or more claims of the '377 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

Reservation of Additional Defenses

Tolmar reserves any other defenses, at law or in equity, that may be available now or may become available in the future based on discovery or any other factual investigation in this action.

COUNTERCLAIMS

As separate and independent Counterclaims against Galderma Laboratories, L.P., Galderma S.A. and Galderma Research and Development, S.N.C. (hereinafter collectively, "Plaintiffs/Counterclaim-Defendants"), Tolmar Inc. ("Tolmar") hereby alleges as follows:

The Parties

1. Upon information and belief, Plaintiff/Counterclaim-Defendant Galderma Laboratories, L.P. purports to be a Texas limited partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas. (Complaint, Paragraph 1.)

2. Upon information and belief, Plaintiff/Counterclaim-Defendant Galderma Research S.A. purports to be a Swiss company having a principal place of business at World Trade Center, Avenue de Gratta-Paille 1, Case Postale 552, 1000 Lausanne 30 Grey. (Complaint, Paragraph 2.)

3. Upon information and belief, Plaintiff/Counterclaim-Defendant Galderma Research and Development, S.N.C. purports to be a French company having a principal place of business at 2400 Route Des Colles, Les Templiers, 06410 Biot France. (Complaint, Paragraph 3.)

4. Tolmar is a corporation organized and existing under the laws of Delaware with its principal place of business at 701 Centre Avenue, Fort Collins, Colorado.

Jurisdiction and Venue

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants at least because they have availed themselves of the rights and privileges of this forum by suing Tolmar in this District in relation to this action, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Factual Background

9. U.S. Patent No. 7,579,377 (“the ‘377 patent”) is entitled “Administration of 6-[3-(1-Adamantyl)-4-methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders” and was issued on August 25, 2009.

10. Plaintiff/Counterclaim-Defendant Galderma Research and Development, S.N.C. purports to be the owner of the '377 patent. (Complaint, Paragraph 3).

11. The Orange Book lists "Galderma Labs LP" as the holder of an approved New Drug Application ("NDA") No. 21-753 for Differin[®] topical gel including the active ingredient of adapalene at a strength of 0.3%, and the Orange Book lists the '377 patent for Differin[®].

12. Tolmar filed ANDA No. 200298 with the FDA under 21 U.S.C. §355(j) for the approval of a 3% adapalene topical gel ("Tolmar's Gel") before the expiration of the '377 patent. Tolmar filed a Paragraph IV Certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), alleging that the claims of the '377 patent will not be infringed by the manufacture, use, sale, offer for sale or import of Tolmar's Gel that is the subject of ANDA No. 200298.

13. On January 21, 2010, Plaintiffs/Counterclaim-Defendants filed a Complaint against Tolmar in this District alleging infringement of the '377 patent due to the filing of Tolmar's ANDA No. 200298, and seeking a declaratory judgment based on their alleged apprehension of infringement due to the manufacture, use, sale, offer for sale or import of Tolmar's Gel after the FDA approves ANDA No. 200298.

14. As evidenced by Plaintiffs' Complaint and Tolmar's Answer and Defenses thereto, there is an actual, substantial and continuing justiciable case or controversy between the parties regarding infringement and invalidity of the claims of the '377 patent.

Count I
(Declaratory Judgment of Non-Infringement of the '377 Patent)

15. Tolmar restates paragraphs 1-14 of these Counterclaims as if set forth fully herein.

16. Plaintiffs/Counterclaim-Defendants have alleged that Tolmar has infringed the '377 Patent, and Tolmar has denied this allegation.

17. Tolmar's filing of ANDA No. 200298 has not directly or indirectly infringed any valid claim of the '377 patent, either literally or under the doctrine of equivalents.

18. Tolmar's proposed activities after approval of ANDA No. 200298 would not directly or indirectly infringe any valid claim of the '377 patent, either literally or under the doctrine of equivalents.

19. Tolmar is entitled to a judicial determination that Tolmar's filing of ANDA No. 200298 does not result in infringement of any valid claim of the '377 patent and the proposed Tolmar generic 3% adapalene topical gel product ("the Tolmar Gel") that is the subject of ANDA No. 200298 have not, and would not, directly or indirectly infringe any valid claim of the '377 patent if made, used, sold, offered for sale and/or imported into the United States, either literally or under the doctrine of equivalents.

20. Further, the doctrine of prosecution history estoppel bars the expansion of the claims of the '377 patent to encompass the Tolmar Gel.

21. Therefore, for this additional reason, Tolmar is entitled to a judicial determination that it will not directly or indirectly infringe any valid claim of the '377 patent,

under the doctrine of equivalents, by making, using, selling, offering for sale or importing any product into the U.S. that is the subject of Tolmar's ANDA No. 200298, nor do Tolmar's activities relating to the filing of ANDA No. 200298 result in infringement of any valid claim of the '377 Patent.

Count II
(Declaratory Judgment of Invalidity of the '377 Patent)

22. Tolmar restates paragraphs 1-14 of these Counterclaims as if set forth fully herein.

23. One or more of the claims of the '377 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

24. Tolmar is entitled to a judicial determination that one or more claims of the '377 patent are invalid for failure to comply with the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Tolmar respectfully prays for judgment as follows:

(i) Dismissal of Plaintiffs' Complaint with prejudice and entry of judgment in favor of Tolmar;

(ii) Judgment that the '377 patent claims were not infringed by Tolmar's filing of ANDA No. 200298 and that the proposed Tolmar Gel that is the subject of ANDA No. 200298 has not, and would not, directly or indirectly infringe any valid claim of the '377 patent if made,

used, sold, offered for sale and/or imported into the United States, either literally or under the doctrine of equivalents;

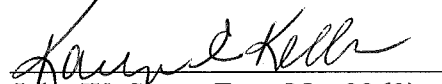
(iii) Judgment that one or more claims of the '377 patent is invalid under one or more of the statutory provisions of Title 35 of the United States Code;

(iv) An award to Tolmar of its costs;

(v) Judgment that this is an exceptional case and an award to Tolmar of its reasonable attorneys' fees and costs under 35 U.S.C. § 285 and/or the inherent discretion of the Court; and

(vi) Such further relief as this Court may deem just, equitable and appropriate.

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Dated: February 12, 2010

CERTIFICATE OF SERVICE

I, Karen Keller, Esq., hereby certify that on February 12, 2010, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on February 12, 2010, I caused a copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following in the manner indicated:

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